REMARKS/ARGUMENTS

Claims 1 to 50 were previously pending and undergoing examination on the merits. With entry of the present Amendment, claims 1, 5, 11, 18, 22, 39, 30, 31, 35 and 39 have been amended, and claims 2, 3, 9, 10, 12-14, 19, 20, 27-29, 32-34, 36, 37, 44, 45, 49 and 50 have been canceled without prejudice to further prosecution. Support for the amendments made to the claims can be found in the specification and claims as originally filed and, thus, no new matter is introduced. Reconsideration is respectfully requested in view of the amendments to the claims and the following remarks.

In the Office Action, the Examiner has indicated that color photographs and color drawings are not accepted unless a petition is filed under 37 C.F.R. 1.84(a)(2). It is unclear from the Office Action whether all that is needed to respond is the petition or the petition and drawings. If the Examiner could clarify what is needed, Applicants would be happy to provide the Examiner with whatever is needed.

Claims 1 to 50 stand rejected, in various combinations, under 35 U.S.C. § 112, first and second paragraphs, and under 35 U.S.C. § 103. For the reasons set forth herein, each of these rejections is overcome.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1-50 are rejected under 35 U.S.C. §112, second paragraph, because the Examiner alleges that the specification while being enabling for a method of determining the presence of a microbe in a sample, wherein the method is practiced in accordance with the method steps of claims 1, 2 and 8, does not provide enablement for any and all manner of "determining" for any life form under any condition (*see*, page 3 of the Office Action). To the extent that the rejection applies to the amended claims, Applicants respectfully traverse this rejection.

The enablement requirement under 35 U.S.C. § 112, first paragraph requires that the specification must teach those of skill in the art how to make and use the invention. As stated

in the MPEP at § 2164.08, "[A]ll that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art" (emphasis added).

In order to expedite prosecution and without commenting on or agreeing to the substance of the Examiner's enablement rejection, Applicants have amended the independent claims, as suggested by the Examiner, to be directed to methods of detecting a microbial organism of interest, and to recite that the detectable molecular probe is peptide nucleic acid and that the binding partner is an antibody. As explained below in connection with the §112, second paragraph, rejection, it is clear from the teachings of the specification that the detectable molecular probe can be detected either directly or indirectly and, thus, the limitation of claim 8 was not incorporated into the independent claims. Based on the teachings of the specification, together with the general knowledge in the field, those of skill in the art can practice the claimed invention without undue experimentation.

In view of the amendments to the claims and the foregoing remarks, the Examiner's enablement concerns are overcome. Accordingly, Applicants urge the Examiner to withdraw the rejection under 35 U.S.C. § 112, first paragraph.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1, 4, 7, 21, 22, 24-35, 38, 39 and 41-50 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The Examiner's concern and, in turn, Applicants' responses to those concerns are set forth below.

The test for indefiniteness is "whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity" (MPEP § 2173.02). This analysis does not occur in a vacuum, but rather in view of the following factors: (1) the content of the particular application disclosure; (2) the teachings of the prior art; and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. In addition, "the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope" (MPEP § 2173.02).

a. The Examiner has objected to the use of the term "detectable molecular probe," alleging that the metes and bounds of this term are unclear. In addition, the Examiner has find it confusing that the "'detectable molecular probe' is not required to be labeled, yet is 'detectable'".

In order to expedite prosecution, all of the pending independent claims have been amended to recite that the detectable molecular probes are peptide nucleic acid. Moreover, as set forth in the specification, all of the molecular probes are "detectable," but they can be directly detected or indirectly detected. If directly detected, the molecular probe is labeled with a detectable moiety (*e.g.*, a chromorphore, a fluorochrome, *etc.*). However, if indirectly detected, the molecular probe is not labeled with a detectable moiety, but instead is detected by other means. For instance, the complex formed between the molecular probe and the target sequence of the microbial organism of interest can be detected using an antibody raised to bind to the probe/target sequence complex (*see*, the specification at page 13, lines 9-20, entitled "Unlabeled Molecular Probes"). Thus, the specification makes it clear that even an "unlabeled" probe can be detected.

In view of the amendment to the independent claims and in view of the teachings in the specification, the use of the term "detectable molecular probe" is clear and, thus, the Examiner's concern is overcome. Accordingly, Applicants urge the Examiner to withdraw this portion of the rejection under 35 U.S.C. § 112, second paragraph.

b. The Examiner has objected to claims 5, 22 and 39, stating that there is no antecedent support for "target sequence" and that the embodiment claimed needs to parallel more closely the disclosed invention.

In order to expedite prosecution, claims 5, 22 and 39 have been amended to recite more specifically that the molecular probe is detected using "a detectable antibody that specifically binds to a complex of the detectable molecular probe and the target sequence of the microbial organism of interest." As explained above, the detectable molecular probe can be directly or indirectly detected. If indirectly detected, the molecular probe is not labeled with a detectable moiety, but instead is detected by other means. In the embodiment recited in claims 5, 22 and 39, the complex formed between the molecular probe and the target sequence of the

microbial organism of interest is detected using an antibody raised to bind to the probe/target sequence complex (*see*, the specification at page 13, lines 9-20, entitled "Unlabeled Molecular Probes").

In view of the amendments to claims 5, 22 and 29 and in view of the teachings in the specification, the Examiner's concern is overcome. Accordingly, Applicants urge the Examiner to withdraw this portion of the § 112, second paragraph, rejection.

c. The Examiner has objected to claim 11, stating that certain members of the Markush group are indefinite.

In order to expedite prosecution, claim 11 has been amended to delete the term "array" from the Markush group recited therein. As the Examiner has pointed out, the specification makes it clear that the solid supports can be arranged in an array format (at, *e.g.*, addressable or identifiable locations), but the array itself is not a solid support.

In view of the amendment to claim 11, the Examiner's concern is overcome. Accordingly, Applicants urge the Examiner to withdraw this portion of the § 112, second paragraph, rejection.

Rejection Under 35 U.S.C. § 103

a. Claims 1, 2, 4, 5, 7-19, 21, 22, 24-36, 38, 39, 41-50 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over Wallner *et al.* (*System. Appl. Microbiol.* 19, 569-56 (1996)) in view of Fulton *et al.* (Clinical Chemistry, 43(9):1749-1756 (1997)), Stender *et al.* (*Journal of Clinical Microbiology*, 37(9):2760-2765 (1999)), Nordentoft *et al.* (*Journal of Clinical Microbiology*, 35(10):2642-2648 (1997)) and McLaughlin (U.S. Patent No. 4,683,196). To the extent that the rejection applies to the amended claims, Applicants respectfully traverse this rejection.

Without acquiescing to the merits of the ***prima facie*** obviousness case and in the spirit of expediting prosecution, independent claims 1, 18, and 35 have been amended to incorporate the limitations of claims 3, 20 and 37, respectively. In addition, independent claims 1, 18 and 35 have been amended to incorporate the limitations of claims 9, 27 and 44, respectively. In view of the amendments to the claims, the foregoing obviousness rejection is

overcome. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. § 103(a).

b. Claims 3, 6, 20, 23, 37 and 40 are rejected under 35 U.S.C. § 103 (a) as allegedly being obvious over Wallner *et al.* (*System. Appl. Microbiol.* 19, 569-56 (1996)) in view of Fulton *et al.* (Clinical Chemistry, 43(9):1749-1756 (1997)), Nordentoft *et al.* (*Journal of Clinical Microbiology*, 35(10):2642-2648 (1997)), McLaughlin (U.S. Patent No. 4,683,196) and further in view of Stender *et al.* (*Journal of Clinical Microbiology*, 37(9):2760-2765 (1999)). To the extent that the rejection applies to the amended claims, Applicants respectfully traverse this rejection.

A claim is considered obvious "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains" (35 USC § 103(a)). The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395-97 (2007) identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham*. The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. § 103 should be made explicit. One of the rationales addressed by the court in KSR supports a finding of obviousness when the prior art reference (or combination of references) (1) teaches or suggests the claim elements; (2) provides some suggestion or motivation to combine the references; and (3) provides a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) and MPEP § 2143.

Again, without acquiescing to the merits of the ***prima facie*** obviousness case and in the spirit of expediting prosecution, independent claims 1, 18, and 35 have been amended to incorporate the limitations of claims 3, 20 and 37, respectively. In addition, independent claims 1, 18 and 35 have been amended to incorporate the limitations of claims 9, 27 and 44,

respectively. As pointed out by the Examiner, the antibody is immobilized on a solid carrier (*e.g.*, a coded beaded support).

Although various elements of the claimed invention can be found in the numerous cited references, Applicants respectfully submit that the cited art does not teach or suggest a method employing the selectivity and discriminating power of an antibody immobilized on a solid carrier (*e.g.*, a coded bead), as used in a capture assay, in combination with the selectivity and discriminating power of a PNA molecular probe, as used to stain microbial organisms, to provide for two independent levels of certainty and/or discrimination. Moreover, the cited art of record, either alone or in combination, does not teach or suggest a significant advantage of the presently claimed methods over the methods of the prior art. As set forth in the specification, one of the advantages of the presently claimed methods is that the use of PNA probes (*i.e.*, molecular probes that are peptide nucleic acids) allows for the harmonization of the hybridization and antibody binding conditions because PNA probes bind more tightly under conditions of physiological salt, conditions under which antibodies are more likely to operate most efficiently.

In view of the foregoing, Applicants respectfully submit that the prior art of record does not teach or suggest the presently claimed methods or the advantages associated with such methods. Absent such teachings or suggestions in the prior art, the claimed invention is non-obvious and, thus, patentable. Accordingly, Applicants urge the Examiner to withdraw the rejection under 35 U.S.C. § 103.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

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